K090187

MAY 12 2009

510 (k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Yuhua Chen
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Date Prepared	Jan 23rd, 2009

2. Name of Device

Trade Names	FORA G30 Blood Glucose Monitoring System
Common Names/Descriptions	Blood Glucose Meter Blood Glucose Test Strips
Classification Names	Class II devices (21 CFR Section 862.1345, Glucose Test System)

3. Predicate Device

Trade/Proprietary Name:	Clever Chek TD-4230 blood glucose monitoring system
Common/Usual Name:	Blood Glucose Meter Blood Glucose Test Strips
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K070472

4. Device Description

FORA G30 Blood Glucose Monitoring System consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

5. Intended Use

FORA G30 Blood Glucose Monitoring System is indicated for the quantitative measurement of glucose in fresh capillary whole blood taken from the finger and the alternative sites for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Testing is done outside the body (in vitro diagnostic use).

The alternative site testing (the plam, the forearm, the upper arm, the calf and the thigh) in this system can be used only during steady-state blood glucose conditions.

6. Comparison to Predicate Device

FORA G30 Blood Glucose Monitoring System has equivalent technological characteristics as the Clever Chek TD-4230 blood glucose monitoring system (K070472). FORA G30 Blood Glucose Monitoring System also has the same intended use as the Clever Chek TD-4230 blood glucose monitoring system

7. Performance Studies

The performance of FORA G30 Blood Glucose Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the performance of this system meets its intended use.

8. Conclusion

FORA G30 Blood Glucose Monitoring System demonstrates satisfactory performance and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 12 2009

TaiDoc Technology Corporation
c/o Yuhua Chen
6F, No. 127, Wugong 2nd Road
Wugu Township, Taipei County
China (Taiwan) 248

Re: k090187
Trade Name: FORA G30 Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: April 22, 2009
Received: April 24, 2009

Dear Yuhua Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K090187

Device Name: FORA G30 Blood glucose monitoring system

Indications for Use:

The FORA G30 Blood glucose monitoring system is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The alternative site testing in the FORA G30 Blood glucose monitoring system can be used only during steady-state blood glucose conditions.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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